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U.S. Department of Justice

United States Attorney Eastern District of New York

MF:RMR F.#2004R01002 271 Cadman Plaza East Brooklyn, New York 11201

April 10, 2009

By Hand Delivery TO BE FILED UNDER SEAL

The Honorable Sterling Johnson, Jr. United States District Judge Eastern District of New York 225 Cadman Plaza East Brooklyn, New York 11201

The Honorable Jack B. Weinstein United States District Judge Eastern District of New York 225 Cadman Plaza East Brooklyn, New York 11201

United States v. Nichols Institute

Diagnostics, Inc.

Criminal Docket No. 09-CR-203

Dear Judge Johnson and Judge Weinstein:

On April 8, 2009, in anticipation of a potential quilty plea by the defendant Nichols Institute Diagnostics, Inc. ("NID"), the government filed an Information Sheet and Notice of Motion pursuant to Rule 7(b) of the Federal Rules of Criminal Procedure in the above-captioned case. On the Information Sheet, the government indicated that the criminal case against NID, which was assigned to Judge Weinstein on April 8, 2009, is related to a pending civil case that bears docket number CV 04-That civil docket number was the number assigned to <u>United</u>

In the Information Sheet and Rule 7(b) Notice, the government captioned the criminal case against NID as United States v. John Doe. The captioning of the case in this manner arises from the fact that, as is discussed herein, the anticipated charge against NID arises from, and relates to, a sealed civil complaint that is pending in this district before Judge Johnson. Prior to the anticipated plea proceeding in this matter, the government intends to request that the Court modify the caption in this case so as to refer to the defendant NID by its true name.

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States ex rel. Thomas Cantor v. Nichols Institute Diagnostics, Inc. ("Cantor"), which is a sealed False Claims Act ("FCA") case currently assigned to Judge Johnson. This letter is respectfully submitted to explain the basis for the government's view that, pursuant to the Administrative Order issued by Chief Judge Dearie on February 27, 2008 (the "Administrative Order"), the anticipated criminal case against NID and the pending Cantor case are related matters, such that the newly-filed criminal case should be reassigned to Judge Johnson.

In the Administrative Order, Chief Judge Dearie set forth the procedure that is to be followed in the assignment of criminal cases, and specifically addressed the requirements that must be satisfied for a criminal case to be related to an already pending case. In particular, the Administrative Order provides, in relevant part:

[N]otwithstanding any provision of Rule 50.3 of the Rules of the Division of Business Among District Judges, the Clerk of the Court is directed to assign all criminal cases randomly, unless the United States Attorney certifies in writing at the time of the filing that a case to be assigned satisfies one of the three conditions in Rule 50.3(c) [of the Rules for the Division of Business Among District Judges], or involves the same specific conduct that is the subject of a pending case.

The criminal information that the government expects to file against NID in this case will allege the felony misbranding of an immunoassay that NID manufactured and sold for measuring the levels of parathyroid hormones in the human bloodstream. This precise conduct - the misbranding of the PTH immunoassay - was one of the subjects of relator Thomas Cantor's FCA case, which was filed in 2004 and has been supervised by Judge Johnson. In fact, although the specific details of the FCA complaint remain under seal, it should be noted that the relator alleges in his FCA complaint, among other things, that NID misbranded its test kits for measuring PTH levels.² The core facts of the anticipated criminal case against NID are thus already contained

In a prior order, Judge Johnson permitted the government to provide NID with certain disclosures regarding the FCA case. Thus, the fact that this letter contains a brief discussion of the FCA complaint and is being provided to NID's counsel is consistent with Judge Johnson's sealing orders.

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in, and are among the subjects of, the FCA case that has been pending under Judge Johnson's supervision for over four years.

Accordingly, pursuant to the Administrative Order relation is appropriate here given the criminal case against NID involves "the same specific conduct that is the subject of a pending case" - namely the FCA currently before Judge Johnson. Counsel for the defendant NID, Jim Walden, Esq., consents to the relation of these cases. Additionally, because this letter makes reference to a FCA case that is still under seal before Judge Johnson, we respectfully request that this letter be and remain under seal as well.

Thank you for your attention to this matter.

Respectfully submitted,

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